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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,035	11/20/2000	Bettina Mockel	P 274441 990169 BT	6847

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EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	13

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/715,035	Mockel et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sh et with th corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above, claim(s) 8-19 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-7 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-7, in Paper No. 12 is acknowledged. The traversal is on the grounds that each of Groups III-VI are related to Group II in the same manner as species are related to a broader genus. This is not found persuasive because as stated in the previous Office Action each of the methods of Groups II-VIII are distinct both physically and functionally and require different process steps, reagents, and parameters.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-7 are under consideration in this Office Action.

Information Disclosure Statement

3. The information disclosure statement filed October 18, 2001, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Copies of the cited references are not present in the application file.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all possible polynucleotides having at least 70% sequence identity to all possible polynucleotides encoding a polypeptide comprising SEQ ID NO: 2 or a polypeptide that is at least 70% identical to SEQ ID NO: 2. The specification, however, only

provides a single representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics for which predictability of structure is apparent. Furthermore, the specification does not disclose the nucleotide sequence that is 5' and 3' of SEQ ID NO: 1 or the amino acid sequence that is N-terminal or C-terminal of SEQ ID NO: 2. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

6. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 or an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1, does not reasonably provide enablement for (1) any isolated polynucleotide having at least 70% sequence identity to a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2 or a polypeptide that is at least 70% identical to SEQ ID NO: 2, (2) any isolated polynucleotide comprising SEQ ID NO: 1, and (3) any isolated polynucleotide encoding any polypeptide comprising SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass (1) any isolated polynucleotide having at least 70% sequence identity to a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2 or a polypeptide that is at least 70% identical to SEQ ID NO: 2, (2) any isolated polynucleotide comprising SEQ ID NO: 1, and (3) any isolated polynucleotide encoding any polypeptide comprising SEQ ID NO: 2. The specification provides guidance and examples for making an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1 and an isolated polynucleotide encoding a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of (1) any isolated polynucleotide having at least 70% sequence identity to a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2 or a

polypeptide that is at least 70% identical to SEQ ID NO: 2, (2) any isolated polynucleotide comprising SEQ ID NO: 1, and (3) any isolated polynucleotide encoding any polypeptide comprising SEQ ID NO: 2 is lacking. Thus, searching for the biological function, biological activity, or utility of said polynucleotides is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said polynucleotides is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said polynucleotides is enormous. Such experimentation entails changing specific nucleotides in SEQ ID NO: 1 (nucleotide deletion, insertion, substitution or combinations thereof) to make a polynucleotide that is at least 70% identical to a polynucleotide that encodes a polypeptide comprising SEQ ID NO: 2 and determining the biological function, biological activity, or utility of the polypeptide. Alternatively, such experimentation includes screening a vast number of organisms for an organism that contains a polynucleotide that is at least 70% identical to a polynucleotide that encodes a polypeptide comprising SEQ ID NO: 2 and determining the biological function, biological activity, or utility of the polypeptide.

Since routine experimentation in the art does not include screening or making vast numbers of polynucleotides which encode polypeptides comprising an amino acid sequence that is at least 70% identical to SEQ ID NO:2, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function relationship of the claimed polynucleotides. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 a), the phrase "70% to a polynucleotide which codes for a polypeptide" renders the claim vague and indefinite because the specific nucleotide sequence of the polynucleotide which "codes for a polypeptide" is not known and not defined in the specification. Claims 2-4 and 6 which depend from claim 1 are also rejected because they do not correct the defect of claim

1.

In claim 6 (ii), the phrase "within the range of the degeneration of the genetic code" renders the claim indefinite because the meaning of the phrase is not known and not defined in the specification. In part (iii) the specific hybridization conditions are not known and not stated in the claim. In part (iv), the phrase "sense mutations of neutral function" renders the claim vague and indefinite because the specific mutations are not known and the meaning of the phrase are not known and defined in the specification.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Oliver et al.

Claim 1-3 are anticipated by Oliver et al. (Accession Z99263) since Oliver et al. teach a polynucleotide containing at least 15 successive nucleotides of a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 (see Alignment No. 1). Thus, the reference teaching anticipates the claimed invention.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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